

## **Small Business Regulatory Fairness Board Small Business Impact Statement**

**Date:** August 30, 2016

**Rule Number:** 20 CSR 2220-2.095- Collection of Non-Controlled Medication for Destruction

**Name of Agency Preparing Statement:** DIFP, Professional Registration, State Board of Pharmacy

**Name of Person Preparing Statement:** Kimberly Grinston

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**Name of Person Approving Statement:** Kathleen Steele Danner

**Please describe the methods your agency considered or used to reduce the impact on small businesses** (§536.300 RSMo examples: consolidation, simplification, differing compliance, differing reporting requirements, less stringent deadlines, performance rather than design standards, exemption, or any other mitigating technique).

In 2014, the Drug Enforcement Administration (DEA) changed its rule to allow pharmacies and other DEA registrants to accept returned prescription medication. The Board has been working on the proposed rule since the enactment of the DEA rule and gathering public input.

The proposed rule was reviewed by the Board during open session meetings held in April 2015, July 2015, October 2015, January 2016, March 2016 and July 2016. Public comments were accepted during each meeting and incorporated into the rule as deemed appropriate.

**Please explain how your agency has involved small businesses in the development of the proposed rule.**

The proposed rule was reviewed by the Board during open session meetings held in April 2015, July 2015, October 2015, January 2016, March 2016 and July 2016. Public comments were accepted during each meeting and incorporated into the rule as deemed appropriate. Comments from small business were specifically requested. Additionally, the rule was reviewed by Board staff and a Board member who both own and operate small pharmacy businesses in the state.

**Please list the probable monetary costs and benefits to your agency and any other agencies affected. Please include the estimated total amount your agency expects to collect from additionally imposed fees and how the moneys will be used.**

The proposed rule does not establish or include any fees. Accordingly, the Board would not incur any monetary costs/benefits.

**Please describe small businesses that will be required to comply with the proposed rule and how they may be adversely affected.**

Small business pharmacy owners that choose to establish a drug return program would be required to comply with the rule. However, participation is voluntary. No mandatory costs would be imposed.

**Please list direct and indirect costs (in dollars amounts) associated with compliance.**

This proposed amendment will cost an estimated \$306,400 during the first year of implementation and \$35,473.46 annually for the life of the rule. A fiscal note will be filed in accordance with section 536.205, RSMo.

**Please list types of business that will be directly affected by, bear the cost of, or directly benefit from the proposed rule.**

Small business pharmacy owners that choose to establish a drug return program would be required to comply with the rule. However, participation is voluntary. No mandatory costs would be imposed. It should also be noted that pharmacy owners are not prohibited from charging for drug return services and could use the newly created allowance as a revenue generator.

**Does the proposed rule include provisions that are more stringent than those mandated by comparable or related federal, state, or county standards?**

Yes\_\_\_ No\_\_X\_\_

**If yes, please explain the reason for imposing a more stringent standard.**

*For further guidance in the completion of this statement, please see §536.300, RSMo.*